HHS SBIR PAR-14-088

NOTE: The Solicitations and topics listed on this site are copies from the various SBIR agency solicitations and are not necessarily the latest and most up-to-date. For this reason, you should use the agency link listed below which will take you directly to the appropriate agency server where you can read the official version of this solicitation and download the appropriate forms and rules.

The official link for this solicitation is: http://grants.nih.gov/grants/guide/pa-files/PAR-14-088.html

Agency:
Department of Health and Human Services

Release Date:
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Branch:
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Program / Phase / Year:
SBIR / Phase II / 2014

Application Due Date:
September 05, 2015
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September 05, 2016
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Solicitation:
PAR-14-088

Close Date:
January 07, 2017 (closing in 404 days)
Topic Number:
PAR-14-088

Description:

The SBIR/STTR Programs were recently reauthorized by the United States Congress with the SBIR/STTR Reauthorization Act of 2011 (P.L. 112-81). One change that was made to the SBIR program in this reauthorization was the authority for certain participating federal agencies to 'issue a Phase II award to a small business concern that did not receive a Phase I award for that research/research & development' through FY 2017. This is a so-called 'Direct-to-Phase II' SBIR award. This authority would permit SBCs to submit Direct-to-Phase-II SBIR applications, if the small business had performed the Phase I stage-type of research through other funding sources. The legislative rationale for permitting the Direct-to-Phase II award is to allow a SBC that has already built a technology prototype and tested its feasibility (i.e. completed Phase-I-type R&D) to move directly into a Phase-II-type R&D that tests the functional viability of the prototype according to scientific methods and potential for commercial development. The Direct-to-Phase-II SBIR mechanism eliminates the need for the SBCs to propose additional small feasibility studies, if the technology is ready for the Phase II stage of development. The Direct-to-Phase II authority is **not** available to the STTR program.

The purpose of this funding opportunity announcement (FOA) is to implement the Direct-to-Phase II

SBIR mechanism at NIH. For this FOA, the small business has demonstrated the scientific and technical merit and feasibility of the prototype stage of developing a biomedical technology that has commercial potential. The goal of this FOA is to enable a small business that has accomplished the objectives of a Phase I SBIR grant through non-SBIR funds to initiate the Phase II SBIR stage of development, without needing to perform more early stage, Phase-I-SBIR-type research.

Only the NIH Institutes and Centers listed in Components of Participating Organizations above will accept Direct-to-Phase II SBIR submissions under this FOA.

This FOA will also **not** accept 'regular' Phase II submissions from SBCs that have received a Phase I SBIR or STTR award from NIH or any other agency that participates in the SBIR/STTR programs for projects for which applicants now seek follow-on research and development funding.

For this FOA, it is expected that the technology, prototype, or method will have passed the proof of principle stage and that the product has demonstrated feasibility and supports a Phase II effort. Data or evidence of the capability (including a statement of any Phase I-like quantitative milestones), completeness of design, and efficacy must be provided in the application, along with the rationale for selection of the criteria used to validate the technology, prototype, or method, similar to a Phase I final report required in standard Phase II applications.

NIH Institutes and Centers participating in this FOA may accept Direct-to-Phase II SBIR applications based on any topic within their mission **OR** based on specific topics.

With the exception of NINDS, all participating NIH Institutes and Centers will accept will accept Direct-to-Phase II SBIR applications in this FOA for **any** biomedical/behavioral technology areas within their mission as can be found in the NIH SBIR/STTR Program Descriptions and Research Topics http://grants.nih.gov/grants/funding/sbirsttr1/2014-2_SBIR-STTR-topics.pdf.

National Institute of Neurological Disorders and Stroke (NINDS) will accept Direct-to-Phase II SBIR applications in this FOA **only** based the specific topic areas listed below:

The NINDS SBIR/STTR program funds small business concerns to conduct innovative neuroscience research and/or development (R/R&D) that has both the potential for commercialization and public benefit. The NINDS accepts a broad range of small business applications that are significant, innovative, and relevant to its mission. Examples of research topics within the mission of NINDS are shown below. This list is not all inclusive and some research areas fall into multiple categories.

1. Therapeutics and Diagnostics Development for Neurological Disorders, including biomarker and diagnostic assays, therapeutics (drugs, biologics, and/or devices) for treatment of neurological disorders, and technologies/methodologies to deliver therapeutics to the nervous system.

2. Clinical and Rehabilitation Tools, including intraoperative technologies for neurosurgeons, rehabilitation devices and programs for neurological disorders, and brain monitoring systems

3. Technology and Tools, including technologies to image the nervous system, neural interfaces technologies, and tools for neuroscience research and drug development.

Clinical Trials: NINDS will **not** accept applications that include clinical trials. A clinical trial is a prospective biomedical or behavioral research study of human subjects designed to answer specific questions about safety, tolerability, efficacy and/or effectiveness of pharmacologic, behavioral, biologic, surgical, or device (invasive or non-invasive) interventions. This policy does not apply to (1) exploratory IND studies as defined by the FDA (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm078933.pdf) or (2) early feasibility studies of devices as defined by the FDA (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm279103.pdf).

NINDS accepts and supports SBIR and STTR clinical trial applications through specific opportunities, which can be found on the NINDS SBIR webpage: http://www.ninds.nih.gov/funding/small-

business/small_business_funding_opportunities.htm. Other human subjects research can be submitted and NINDS may decline funding of any application that includes human subjects for programmatic or administrative reasons. SBIR applicants considering projects involving human subjects research are strongly encouraged to contact program staff.

NIH **strongly** encourages small businesses to contact the appropriate Institute or Center early in their application planning process to ensure their technology is of priority to the Institute/Center.